Special 510(k) Summary

DEC 1 2 2012

Company Name:
SeaSpine, Inc.
An Integra Life Sciences Company
2302 La Mirada Drive
Vista, CA 92081

Contact person:
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Director, Engineering
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Date prepared:
December 11, 2012

Trade name:
Malibu™ Spinal System with the Daytona™ Deformity System

Common name:
Pedicle Screw System

Classification name:
Pedicle Screw Spinal System
MNH (Class II) - 888.3070(b)(1)
MNI (Class II) - 888.3070(b)(1)
NKB (Class III) - 888.3070(b)(2)

Spinal Interlaminal Fixation Orthosis
KWP (Class II) - 888.3050

Predicate Device:
Previously cleared Malibu Spinal System 510(k)'s K072605, K061342, K051942, K051663, Xia Spinal System 510(k) K060979, UCR Spinal System 510(k) K021623 and the IST Pedicle Screw System 510(k) K053276.

Device Description:
The Malibu Spinal System contains titanium alloy and cobalt alloy implants and surgical tools. This submission is intended to address line extensions for spinal rods of identical material composition and dimensional specifications but with a higher tensile strength and varying uni-planar pedicle screws. Additional documentation is submitted for a reduced sterilization time for the Malibu implants within the Daytona™ Deformity System.

Intended use:
The intended use for the Malibu Spinal System remains unchanged by the addition of the product line extension and remains as:

The intended use of the Malibu System when used as a **Pedicle Screw Spinal System or Spondylolisthesis Spinal Fixation Device System**, is to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and

chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The indications for use are as follows:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusions by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion (indication for use only when used as a Spondylolisthesis Spinal Fixation Device System),
- trauma (*i.e.*, fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudarthosis, and/or
- failed previous fusion.

The intended use and indications of the Malibu™ Spinal System, when used as a **Spinal Interlaminal Fixation Orthosis or Hook Spinal System,** are limited to T1-L5 and are as follows:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- spondylolisthesis,
- trauma (*i.e.*, fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudarthosis, and/or
- failed previous fusion.

Technological Characteristics: The spinal rod product line extension increases the ultimate strength of the existing cobalt alloy spinal rods while the varying uni-planar pedicle screws combine the features of the current pedicle screws including cannulated and non-cannulated with variable and limiting angles. These line item extensions to the system do not alter the fundamental scientific technologies of the previously cleared system; these devices have substantially equivalent technological characteristics as the predicate devices. These Malibu rods and pedicle screws are housed within the Daytona™ Deformity sterilization tray. A re-validation to updated standards is included.

Performance Testing: The subjective devices were compared to legally marketed predicated devices in regards to an array of testing per ASTM 1717 (static compressive bending, fatigue compressive bending, static torsion) and ASTM 1798 (static AP) testing and found to be equivalent.

Declaration of Substantial Equivalence:	All verification and validation activities related to the design features, conducted risk analysis, and mitigation activities (e.g. performance testing) showed that the submitted devices are substantially equivalent to predicate devices. The manufacturing facility is in conformance with the design control procedure requirements as specified in 21 CFR §820.30 and the records are available for review.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Letter dated: December 12, 2012

SeaSpine, Incorporated
% Mr. Nicholas M. Cordaro
Director, Engineering
2302 La Mirada Drive
Vista, California 92081

Re: K122571
Trade/Device Name: Malibu™ Spinal System with the Daytona™ Deformity System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWP
Dated: November 1, 2012
Received: November 19, 2012

Dear Mr. Cordaro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K122571

Device Name: Malibu™ Spinal System with the Daytona™ Deformity System

Indications for Use:

The intended use of the Malibu System when used as a **Pedicle Screw Spinal System or Spondylolisthesis Spinal Fixation Device System**, is to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine.

The indications for use are as follows:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
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- spondylolisthesis,
- trauma (*i.e.*, fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),
- spinal tumor,
- pseudoarthrosis, and/or
- failed previous fusion.

Prescription Use ____X__ AND/OR Over-The-Counter-Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K122571

510(k) Number: K122571

Device Name: Malibu™ Spinal System with the Daytona™ Deformity System

Indications for Use (Continued):

The intended use and indications of the Malibu™ Spinal System, when used as a **Spinal Interlaminal Fixation Orthosis or Hook Spinal System,** are limited to T1-L5 and are as follows:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- spondylolisthesis,
- trauma (*i.e.*, fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudarthosis, and/or
- failed previous fusion.

Prescription Use ____X__ AND/OR Over-The-Counter-Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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